

REMARKS

Reconsideration of this patent application in view of the present amendment and these remarks is respectfully requested.

I. Title

The title of the application has been objected to as not descriptive. The title has now been amended to delete the reference to a "method" per the Examiner's comments. The amended title is now descriptive of the invention.

II. Abstract

The abstract has been objected to as improper in that it is a restatement of the first claim. More particularly, the abstract has been objected to as not providing enough details of the technical disclosure to enable one to understand the nature of applicant's invention and the improvement over the prior art.

It is respectfully submitted that the abstract as written complies with the guidelines of §608.01(b) of the Manual of Patent Examining Procedure ("MPEP"). Specifically, the abstract as written is "a concise statement of the technical disclosure of the patent" and does "**include** that which is new in the art to which the invention pertains" [Emphasis added to quoted language from MPEP]. The fact that the abstract is a restatement of claim 1 of the application necessarily means that the abstract includes that which applicant considers to be new in the art to which the invention pertains. The proposal in the Office Action that the abstract should include more details of the technical disclosure is contrary to the guidelines in the MPEP not to give extensive mechanical and design details of apparatus in an abstract. As the

abstract is in compliance with the MPEP guidelines, withdrawal of the objection to the abstract is respectfully requested.

III. **Claims**

Claims 1-44 are currently pending. Claims 1-44 stand rejected. Claim 38 has been objected to. Claim 38 is now amended to clarify the scope of the claimed subject matter. Reconsideration of the above-identified application in view of the amendment to claim 38 and the following remarks is respectfully requested.

1. **Rejection of Claims 1-3 and 5 Under 35 U.S.C. §101**

Claims 1-3 and 5 have been rejected for statutory double patenting under 35 U.S.C. §101 as claiming the same invention as claim 15 of prior U.S. Patent No. 7,128,761 to Kuras et al. (hereinafter, "Kuras"). It is respectfully submitted that claims 1-3 and 5 do not claim the same invention as claim 15 of Kuras.

35 U.S.C. §101 prevents two patents from issuing on the same invention. "Invention" means what is defined by the claims. The "same invention" means "identical subject matter". In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claim 15 of Kuras recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises a resilient core having a first surface and a second surface. A first retaining device is attached to the first surface of the resilient core. The first retaining device has an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. A second retaining device is fixedly connected to the second surface of the resilient core. The second retaining device has an outer surface engageable with a second vertebra of the spinal column and an inner surface facing the second

surface of the resilient core. The inner surface of the first retaining device is spaced from the core, and the core deflects into engagement with the inner surface of the first retaining device upon relative movement between the first and second retaining devices. The first retaining device includes a first mounting member engageable with the first vertebra and a first retaining member. The first retaining member has the outer surface engageable with the first vertebra and an inner surface affixed to the first surface of the core. The first mounting member includes the inner surface facing the core that the core engages upon relative movement between the first and second retaining devices. One of the first retaining member and the first mounting member includes a guide engageable with another of the first retaining member and the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

As can be seen from the foregoing, claim 15 of Kuras recites that the inner surface of the first retaining device is spaced from the core and that the core deflects into engagement with the inner surface of the first retaining device upon relative movement between the first and second retaining devices. Claims 1-3 and 5 of the present application do not include such a recitation. Thus, the claimed invention of claims 1-3 and 5 is not the same as the claimed invention of claim 15 of Kuras. Consequently, claims 1-3 and 5 of the present application are not claiming the same invention as claim 15 of Kuras, and it is respectfully requested that the rejection of claims 1-3 and 5 for statutory double patenting under 35 U.S.C. §101 be withdrawn.

2. Rejection of Claims 1-3, 5-13, 16-21, 23-29 and 32-34 Under 35 U.S.C. §102(b)

Claims 1-3, 5-13, 16-21, 23-29 and 32-34 have been rejected as anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,893,889 to Harrington (hereinafter, "Harrington"). It is respectfully submitted that claims 1-3, 5-13, 16-21, 23-29 and 32-34 are novel over Harrington.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

Claim 1 recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises an artificial disc that includes a resilient core having a first surface and a second surface. A first retaining member is connected to the first surface of the resilient core. A second retaining member is connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface facing the second surface of the resilient core. A first mounting member is connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member is engageable with the

artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

The Office Action states that Harrington discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Harrington comprises an artificial disc (disc 18 of Harrington) that includes (a) a resilient core (member 68 of Harrington) having a first surface and a second surface, (b) a first retaining member (member 32 of Harrington), and (c) a second retaining member (member 34 of Harrington). The Office Action also states that the first retaining member of Harrington has an outer surface (surface 36 of Harrington) and an inner surface (surface 58 of Harrington) and that the second retaining member of Harrington has an outer surface (surface 40 of Harrington) and an inner surface (surface 44 of Harrington). Lastly, the Office Action asserts that the apparatus of Harrington comprises a first mounting member (screws 64 and 66 of Harrington) connectable with the first vertebra to position the artificial disc between the first and second vertebrae and engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

It is respectfully submitted that Harrington does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Harrington as required by 35 U.S.C. §102(b). As stated at column 4, lines 22-27 of Harrington, the prosthesis disc 18 of Harrington is inserted around the spinal cord of a patient and between upper and lower vertebrae by a surgeon. Once the prosthesis 18 is properly positioned between the vertebrae, the surgeon tightens the screws in

place using a right angle drilling tool. As shown in Fig. 2 of Harrington and described at column 3, lines 52-57 of Harrington, the screws 64 and 66 extend through holes 53, 54, 60 in the collar 54 and base 49 that comprise the upper member 32. Thus, the screws 64 and 66 of Harrington, which the Office Action asserts are the "mounting member" of Harrington, engage the prosthesis disc 18 before being connected to the first vertebra by the surgeon, rather than after being connected to the vertebrae as recited in claim 1. Similarly, the screws 64 and 66 of Harrington do not guide movement of the artificial disc into position between the first and second vertebrae as recited by claim 1 because the surgeon has already positioned the prosthesis disc 18 of Harrington before the screws are tightened in place. Since Harrington does not disclose these elements of claim 1, Harrington cannot anticipate claim 1 under 35 U.S.C. §102(b). Claim 1 is therefore novel and allowable over Harrington.

Claims 2-3, 5-13, 16-21, 23-29 and 32-34 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 2-3, 5-13, 16-21, 23-29 and 32-34 define over Harrington, and withdrawal of this rejection of claims 2-3, 5-13, 16-21, 23-29 and 32-34 is respectfully requested.

**3. Rejection of Claims 1-4, 19-22, 35-36 and 39-40 Under
35 U.S.C. §102(b)**

Claims 1-4, 19-22, 35-36 and 39-40 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,156,067 to Bryan et al.

(hereinafter, "Bryan"). It is respectfully submitted that claims 1-4, 19-22, 35-36 and 39-40 are novel over Bryan.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 927 F.2d 1565 18, USPQ2d 1001 (Fed. Cir. 1991).

Claim 1 recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises an artificial disc that includes a resilient core having a first surface and a second surface. A first retaining member is connected to the first surface of the resilient core. A second retaining member is connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface facing the second surface of the resilient core. A first mounting member is connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member is engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

The Office Action states that Bryan discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Bryan comprises an artificial disc that includes (a) a resilient core (central portion 24 of body 20 of Bryan) having a first surface and a second surface, (b) a first retaining member (support 32 of Bryan), and (c) a second retaining member (support 34 of Bryan). The Office Action also states that the first retaining member of Bryan has an outer surface (surface 52 of Bryan) and an inner surface (surface 62 of Bryan) and that the second retaining member of Bryan has an outer surface (surface 54 of Bryan) and an inner surface (surface 64 of Bryan). Lastly, the Office Action asserts that the apparatus of Bryan comprises a first mounting member (screw 92 of Bryan) connectable with the first vertebra to position the artificial disc between the first and second vertebrae and engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

It is respectfully submitted that Bryan does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Bryan as required by 35 U.S.C. §102(b). As stated at column 7, lines 2-9 of Bryan, the concaval-convex elements of Bryan (which, as described at column 4, lines 10-19, are the supports 32 and 34) are inserted between two milled vertebrae 12 and 14. The elements 32 and 34 are then attached by anchors 102 and 104 to the bone. As shown in Fig. 3 of Bryan and described at column 4, lines 31-34 of Bryan, the anchors 102 and 104 receive screws 92 and 94 that extend through openings in the elements 32 and 34. Thus, the screw 92 of Bryan, which the Office Action asserts is

the "mounting member" of Bryan, is engaged with the disc endoprosthesis 18 before being connected to the first vertebra via the anchor 102, rather than after being connected to the vertebrae as recited in claim 1. Similarly, the screw 92 of Bryan does not guide movement of the disc endoprosthesis 18 into position between the first and second vertebrae as recited by claim 1 because the elements 32 and 34 of the disc endoprosthesis 18 of Bryan have already been positioned before the screw 92 is inserted into the anchor 102. Since Bryan does not disclose these elements of claim 1, Bryan cannot anticipate claim 1 under 35 U.S.C. §102(b). Claim 1 is therefore novel and allowable over Bryan.

Claims 2-4, 19-22, 35-36 and 39-40 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the immediately preceding discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 2-4, 19-22, 35-36 and 39-40 define over Bryan, and withdrawal of this rejection of claims 2-4, 19-22, 35-36 and 39-40 is respectfully requested.

4. Rejection of Claims 1, 14-15, 19 and 30-31 Under 35 U.S.C. §103(a)

Claims 1, 14-15, 19 and 30-31 have been rejected as unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,401,269 to Büttner-Janz et al. (hereinafter, "Büttner-Janz") in view of Bryan and U.S. Patent No. 6,296,664 to Middleton (hereinafter, "Middleton"). It is respectfully submitted that claims 1, 14-15, 19 and 30-31 define over the cited art.

Pursuant to 35 U.S.C. §103, even though the invention is not identically disclosed or described as set forth in 35 U.S.C. §102, a patent may not be obtained

if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. When considering nonobviousness under 35 U.S.C. §103, the U.S. Supreme Court held in Graham v. John Deere Co., 383 U.S. 1 (1966) that:

- a) that the scope and content of the prior art are to be determined;
- b) the differences between the claims at issue and the prior art are to be ascertained; and
- c) the level of ordinary skill in the pertinent art is to be resolved.

The Office Action states that Büttner-Janz discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Büttner-Janz comprises an artificial disc that includes (a) a core (core 3 of Büttner-Janz) having a first surface and a second surface, (b) a first retaining member (plate 2 of Büttner-Janz), and (c) a second retaining member (plate 1 of Büttner-Janz). The Office Action also states that the first retaining member of Büttner-Janz has an outer surface and an inner surface and that the second retaining member of Büttner-Janz has an outer surface and an inner surface. The Office Action notes that Büttner-Janz fails to teach (a) that the core is a resilient core and (b) the use of a first and second mounting member. The Office Action then states that Bryan teaches an apparatus where the core is a resilient core and that Middleton teaches an apparatus with a first mounting member (end cap 104 of Middleton) and a second mounting member (end cap 106 of Middleton). Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Büttner-Janz (a) with a resilient core, as suggested by

Bryan, as doing so would enable the apparatus to more accurately mimic the natural movement of the spinal column by allowing compression and (b) with a first and second mounting member, as suggested by Middleton, as doing so could limit or enhance compression of the resilient core.

The Office Action hypothesizes that one of ordinary skill in the art would have found it obvious to modify the apparatus of Büttner-Janz with the end caps 104 and 106 of Middleton as doing so could enhance or limit compression of the core of Büttner-Janz, which the Office Action first proposes to make resilient with the resilient core of Bryan. It is respectfully submitted that one of ordinary skill in the art would not have considered the hypothesized modifications of Büttner-Janz.

The prosthesis 100 of Middleton has no core, but instead relies on slits 122 in an exterior wall 112 to permit the wall to elastically deform when subjected to load (see claim 1 of Middleton). Because there is no core, Middleton can provide two end caps 104 and 106 in the center of prosthesis 100 with engagement surfaces 142 and 144 that contact each other during high loads to provide an alternate load path through the center of the disc, as described at column 4, lines 7-13 of Middleton.

In order to use the end caps 104 and 106 of Middleton to limit compression of the more resilient, modified core 3 of Büttner-Janz, large holes would have to be cut into the plates 1 and 2 and the core 3 of Büttner-Janz to accept the end caps of Middleton and permit the end caps to contact one another to limit compression. Removal of such a substantial portion of the modified, now resilient core 3, in particular, will diminish its structural strength - an issue not faced by the disc of Middleton, which uses an exterior wall 112 fabricated from a suitable rigid material

such as stainless steel. Moreover, as the end plates 1 and 2 of Büttner-Janz slide relative to the core 3, as described, for example, at column 2, lines 15-17 of Büttner-Janz, the hypothesized modification of the apparatus of Büttner-Janz with the resulting projection of the ends caps of Middleton through the core of Büttner-Janz would interfere with its functioning. Thus, one of ordinary skill in the art would not seek to modify the apparatus of Büttner-Janz with the resilient core of Bryan and with the end caps 104 and 106 of Middleton because such modifications would involve substantial structural changes to the apparatus of Büttner-Janz, would weaken the apparatus structurally, and would interfere with its intended functioning.

In addition to the foregoing, as set out previously with respect to the rejections of claim 1 as being anticipated under 35 U.S.C. §102(b) by Harrington and by Bryan, the apparatus of claim 1 comprises a first mounting member connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member of claim 1 is engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

The Office Action asserts that the end cap 104 of Middleton corresponds to the first mounting member of claim 1. As set out in the preceding paragraphs, there is no teaching or suggestion to modify the apparatus of Büttner-Janz by adding the end cap 104 of Middleton. Even if there were such a teaching or suggestion, the end cap 104 of Middleton is inserted into an opening 118 in a support surface 108, as described at column 3, line 60 through column 4, line 16 of Middleton, so as to be generally flush with the surface and provide additional surfaces 134 for bone

attachment. Unlike the first mounting member of claim 1, the end cap 104 of Middleton is not engageable with an artificial disc after being connected to a first vertebra to guide movement of the artificial disc into position between first and second vertebrae. Rather, the end cap 104 of Middleton is inserted into the support surface 108 of the body member 102 before the prosthesis 100 of Middleton is inserted between two vertebrae. Because the end cap 104 of Middleton is attached to the body member 102 of the prosthesis before the prosthesis is inserted between two vertebrae, the end cap 104 also cannot guide the artificial disc into position between the vertebrae, as is also required by claim 1.

The modification of the apparatus of Büttner-Janz that is proposed in the Office Action by adding the end cap 104 of Middleton to the apparatus of Büttner-Janz would suffer from the same deficiency as the apparatus of Middleton. Specifically, the end cap 104 of Middleton would be inserted into the plate 2 of the apparatus of Büttner-Janz before the apparatus is inserted between two vertebrae. Because the end cap 104 of Middleton would be attached before the hypothetical modified apparatus of Büttner-Janz is inserted between two vertebrae, the end cap 104 also would not guide the apparatus into position between the vertebrae, as is also required by claim 1. Claim 1 is therefore neither suggested nor taught by the proposed combination of references and is allowable over the cited art.

Claims 14-15, 19 and 30-31 depend, directly or indirectly, from claim 1, and are allowable for at least the reasons given in the preceding discussion of claim 1 and further for the recitations contained in those claims. It is therefore respectfully

submitted that claims 14-15, 19 and 30-31 define over the cited art, and withdrawal of the rejection of claims 14-15, 19 and 30-31 is respectfully requested.

5. Rejection of Claims 37 and 38 Under 35 U.S.C. §103(a)

Claims 37 and 38 have been rejected as unpatentable under 35 U.S.C. §103(a) over Bryan in view of U.S. Patent No. 4,309,777 to Patil (hereinafter, "Patil"). It is respectfully submitted that claims 37 and 38 define over the cited art.

The Office Action states that Bryan discloses an apparatus as defined in claim 1 but does not teach a flange located on the retaining members. According to the Office Action, Patil teaches an intervertebral disc wherein a first retaining member (disc portion 12 of Patil) includes a flange extending toward a second retaining member (disc portion 14 of Patil) and having a radially inner surface facing a core (compression springs 16 of Patil) and spaced from the core. The Office Action also states that Patil's second retaining member (disc portion 14 of Patil) includes a flange extending toward the first retaining member (disc portion 12 of Patil) and having a radially inner surface facing the core and spaced from the core. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the retaining members 42 and 44 of Bryan to include a flange extending toward the other retaining member, as suggested by Patil, as doing so would restrict the amount of compression of which the core is capable and allow the resulting apparatus to more closely imitate the natural motion of the vertebrae.

As previously explained with respect to the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) by Bryan, Bryan does not disclose the

apparatus of claim 1, and claim 1 is novel over Bryan. Claims 37 and 38 depend, directly or indirectly, from claim 1, and are allowable for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(b) by Bryan and further for the recitations contained in those claims. It is thus respectfully submitted that claims 37 and 38 define over the cited art, and withdrawal of the rejection of claims 37 and 38 is respectfully requested.

6. Rejection of Claims 41-44 Under 35 U.S.C. §103(a)

Claims 41-44 have been rejected as unpatentable under 35 U.S.C. §103(a) over Harrington in view of U.S. Patent No. 5,314,477 to Marnay (hereinafter, "Marnay"). It is respectfully submitted that claims 41-44 define over the cited art.

The Office Action states that Harrington discloses an apparatus as defined in claim 1 but does not teach retaining members engageable with a surgical tool. According to the Office Action, with respect to claims 41 and 43, Marnay teaches an intervertebral disc prosthesis wherein a first retaining member (plate 110 of Marnay) includes a portion (holes 115 and 116 of Marnay) engageable with a surgical tool and having an opening into which a portion (rods 812 and 813 of Marnay) of a surgical tool extends. Also, according to the Office Action, with respect to claims 42 and 44, Marnay teaches an intervertebral disc prosthesis wherein a second retaining member (plate 120 of Marnay) includes a portion (holes 125 and 126 of Marnay) engageable with a surgical tool and having an opening into which a portion (rods 822 and 823 of Marnay) of a surgical tool extends. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the retaining members 32 and 34 of Harrington to include openings for a surgical tool, as

suggested by Marnay, to facilitate insertion of the artificial disc into the intervertebral space.

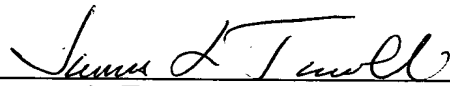
As previously explained with respect to the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) by Harrington, Harrington does not disclose the apparatus of claim 1, and claim 1 is novel over Harrington. Claims 41-44 depend, directly or indirectly, from claim 1, and are allowable for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(b) by Harrington and further for the recitations contained in those claims. It is thus respectfully submitted that claims 41-44 define over the cited art, and withdrawal of the rejection of claims 41-44 is respectfully requested.

IV. Conclusion

In view of the foregoing amendment and remarks, it is respectfully submitted that claims 1-44 define over the cited art. Withdrawal of the rejections of the claims and the passage of the application to issue is therefore requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,


James L. Tarolli
Reg. No. 36,029

TAROLLI, SUNDHEIM, COVELL,
& TUMMINO L.L.P.
1300 East Ninth Street, Suite 1700
Cleveland, Ohio 44114
Phone: (216) 621-2234
Fax: (216) 621-4072
Customer No.: 26,294